UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

May 13, 2022

Memorandum:

Subject: Acute Toxicity Review for EPA File Symbol: 70506-ANT

Applicant:	UPL NA, Inc.
Product Name:	SHENZI™ SC Insecticide
DP Barcode:	D463711
Decision No.:	577860
Action Code:	R310
PC Code(s):	090100 Chlorantraniliprole(34.2%)

From: Odbert Triplett, Biologist
Chemistry, Inerts and Toxicology Assessment Branch (CITAB)
Registration Division (7505P)

Through: Bonaventure Akinlosotu, Ph.D. [eSigned – B.A. Akinlosotu]
Chemistry, Inerts and Toxicology Assessment Branch (CITAB)
Registration Division (7505P)

To: Jasmin Jackson
Venus Eagle, RM 01
Invertebrate-Vertebrate Branch 3
Registration Division (7505P)

Formulation from label:

Active Ingredient(s):	% by wt.
Chlorantraniliprole 3-Bromo-N-[4-chloro-2-methyl-6-[(methylamino)carbonyl]phenyl]- 1-(3-chloro-2-pyridinyl)-1H-pyrazole-5- carboxamide*.....	34.2%
Other Ingredients	65.8%
Total:	100.0%

*Contains 3.33 lb active ingredient per gallon.

ACTION REQUESTED: The Risk Manager requests a review of submitted data to support registration of SHENZI™ SC Insecticide, EPA File Symbol: 70506-ANT.

BACKGROUND: The registrant, UPL NA, Inc., has submitted the following six acute toxicity studies/MRIDs for review: 51623502 (870.1100), 51623504 (870.1200), 51623514 (870.1300), 51623505 (870.2400), 51623503 (870.2500) and 51623506 (870.2600). The registrant is claiming similarity to 279-9606.

The Agency reviewed the data to assess the acute toxicity, irritation, and dermal sensitization potential of the proposed product (see Toxicity Profile under "Comments and Recommendations"). The label of SHENZI™ SC Insecticide, EPA File Symbol: 70506-ANT, indicates that it "is a suspension concentrate that can be applied as a foliar spray, using ground or aerial application to control listed insects".

The application package included a copy of the proposed Basic CSFs (dated September 2, 2021) with Inerts Approved for Food Use under 40 CFR180.910, Pre- and Post-Harvest Application.

RECOMMENDATIONS:

1. All acute toxicity study requirements to support the registration of 70506-ANT have been satisfied by MRIDs 51623502-6 and 51623514.

2. The proposed Basic CSFs submitted for 70506-ANT must be reviewed and accepted by the productchemists in the Chemistry, Inerts and Toxicology Assessment Branch.

3. The registrant is claiming similarity to 279-9606, but since they have submitted new studies, the labeling will be based upon the acute toxicity categories assigned because of the submitted studies and will not rely upon the cited label.

4. While the first aid statements are acceptable they are incomplete. The registrant needs to add the "if on skin or clothing" and "if inhaled" first aid statement (Both acute toxicity category III) followed by the "if swallowed" and "if in eyes" first aid statements (acute toxicity category IV. First aid and precautionary statements need to be listed in order of severity as determined by the acute toxicity category assigned.

5. The phrase "When used as directed this product does not present a hazard to humans or domestic animals" used by the registrant on their label under the Hazards to Humans and Domestic Animals (HHDA) section is not correct and needs to be removed. See page three for the correct precautionary language for the HHDA.

6. The Personal Protective Equipment (PPE) listed is incomplete. The registrant needs to add chemical resistant gloves as listed on page three as the CSF submitted contains a chemical that requires the use of these type of gloves.

7. The following constitutes the toxicology profile assigned to SHENZI™ SC Insecticide, EPA File Symbol: 70506-ANT:

Acute oral toxicity	acceptable	IV	MRID	51623502

Acute dermal toxicity	acceptable	III	MRID	51623504
Acute inhalation toxicity	acceptable	III	MRID	51623514
Primary eye irritation	acceptable	IV	MRID	51623505
Primary dermal	acceptable	IV	MRID	51623503
Dermal sensitization	acceptable	negative	MRID	51623506

Based on the acute toxicity profile given above, with additional information from the CSF and proposed uses, the following are the updated precautionary and first aid statements for 70506-ANT as obtained from the Label Review System:

Product ID: 70506-ANT

Product Name: SHENZI™ SC Insecticide

Precautionary Statements:

Keep out of Reach of Children.

Signal Word: CAUTION Poison Label: None

Hazards to Humans and Domestic Animals:

Harmful if absorbed through skin. Harmful if inhaled.

Avoid contact with skin, eyes or clothing. Avoid breathing (dust, vapor or spray mist). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Personal Protective Equipment (PPE):

- Wear long-sleeved shirt and long pants,
- Socks, shoes
- Chemical-resistant gloves such as: ; Barrier Laminate, Butyl Rubber ≥ 14 mils, Nitrile Rubber ≥ 14 mils, Neoprene Rubber ≥ 14 mils, Polyvinyl Chloride (PVC) ≥ 14 mils, Viton ≥ 14 mils.

Additional labeling should include (but not necessarily be limited to) the following:
Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations:

Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

The Bolded statement above is required in the User Safety Section. The other statements placed in this section by the registrant are acceptable.

First Aid:

If on skin or clothing:
- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If inhaled:
- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.
- Call a poison control center or doctor for treatment advice.

EPA encourages but does not require (see PR Notice 2001-1) registrants to include a company telephone number or toll-free hotline for emergency information in the first aid section. The following are examples of appropriate statements that may be included on the label:

- Have the product container or label with you when calling a poison control center or doctor or going for treatment.
- For medical emergencies, call the poison control center at 1-800-222-1222.
- For general information about this product, call 1-XXX-XXX-XXXX [may include hours of service], or contact the National Pesticides Information Center (NPIC) at 1-800-858-7378, Monday through Friday, 8 AM to 12 PM PST, or at http://npic.orst.edu.

The proposed label includes a telephone number and a statement to have the product container and label when calling to a poison control center or doctor, along with a contact phone number for emergency medical information. These statements are appropriate and acceptable.

EVALUATION RECORD

Reviewers: Odbert Triplett, CITAB **Date:** May 13, 2022
Stephanie J. Garcia, Ph.D. (Summitec Corp.)

Product Reg. No./File Symbol: 70506-ANT

1. DP BARCODE: 463711				
2. PC CODE(S): 090100				
3. CURRENT DATE: May 13, 2022				
4. TEST MATERIAL: GPI 220: Chlorantraniliprole 400 g/L SC; 34.586 ± 0.413% w/w a.i. (405.55 ± 4.84 g/L); Batch/Lot no.: ARD/GPI220/SC/13; JFR Test Item Code: GPI10; off-white color liquid suspension; Density: 1164.4 mg/mL; pH: 6.63 (as a 1% solution in distilled water); Expiration date: September 20, 2022; Stored at room temperature (15 to 30°C).				
Study/ Species/Lab Study #/Date	**MRID**	**Results**	**Tox Cat**	**Core Grade**
Acute oral toxicity/Wistar rat (UDP limit test) Jai Research Foundation (Gujarat, India) Study no. 401-1-01-26664 February 25, 2021 OCSPP 870.1100; OECD 425	51623502	**LD_{50} > 5000 mg/kg bw** 3 fasted female rats were treated with the undiluted test material at a dose level of 5000 mg/kg bw. There were no deaths, abnormal clinical signs, or abnormal gross necropsy findings. All three animals gained weight during both weeks of the study.	**IV**	**A**
Acute dermal toxicity/Sprague Dawley rat Jai Research Foundation (Gujarat, India) Study no. 403-1-01-26665 February 25, 2021 OCSPP 870.1200; OECD 402	51623504	**LD_{50} > 2000 mg/kg bw (both sexes)** 10 rats (5/sex) were dermally exposed for 24 hours to 2000 mg/kg bw of the undiluted test substance. All animals survived, appeared normal, and gained body weight throughout the study. No gross abnormalities were found at necropsy.	**III**	**A**
Acute inhalation toxicity/Wistar rat (4-hour, Nose-only) Jai Research Foundation (Gujarat, India)	51623514	**LC_{50} > 1.751 mg/L (both sexes)** 10 rats (5/sex) were exposed to the test substance diluted with reverse osmosis water (500 mg/mL) and aerosolized at 1.751 mg/L (the	**III**	**A**

Study no. 405-1-01-26666 May 21, 2021 OCSPP 870.1300; OECD 403		maximum achievable breathing zone concentration). Mean gravimetric chamber conc.: 1.751 mg/L; Average MMAD: 3.45 µm; Average GSD: 1.61; Nominal conc.: 8.343 mg/L. All animals survived and gained body weight after initial weight loss during Days 0-1. There were no abnormal clinical signs or abnormal gross necropsy findings.		
Primary eye irritation/New Zealand White rabbit Jai Research Foundation (Gujarat, India) Study no. 407-1-01-26668 February 26, 2021 OCSPP 870.2400; OECD 405	51623505	**MMTS rating could not be determined. No discharge scores were provided.** The undiluted test substance (0.1 mL) was instilled into the right eye of 3 young adult male rabbits. Eyes were anesthetized with proparacaine hydrochloride, and systemic analgesia was provided. No corneal opacity or iritis was observed in any eye during the study. At 1 hour post dose, all treated eyes exhibited conjunctival redness and chemosis (grade = 1) which resolved by 24 hours. There was no positive fluorescein staining at 24 hours. All animals appeared normal for the duration of the study and gained body weight.	**IV**	**A**
Primary dermal irritation/New Zealand White rabbit Jai Research Foundation (Gujarat, India) Study no. 406-1-01-26667 February 25, 2021	51623503	**Slightly Irritating;** **Mean irritation at 1 hr = 1.0;** **PDII = 0.25** 3 male rabbits were dermally exposed to 0.5 mL of the undiluted test material.	**IV**	**A**

OCSPP 870.2500; OECD 404		One hour after patch removal, erythema (score = 1) was observed on all dose sites, resolving by 24 hours. No edema was observed. All animals appeared normal for the duration of the study and gained body weight.		
Dermal sensitization/ Hartley guinea pig (Buehler) Jai Research Foundation (Gujarat, India) Study no. 408-1-01-26669 March 20, 2021 OCSPP 870.2600; OECD 406	51623506	**Is *not* a sensitizer** Based on preliminary screening, 20 guinea pigs (10/sex) were treated with 0.2 mL 100% test substance at induction and challenge; 10 control animals (5/sex) were treated with 0.2 mL distilled water at induction and with 100% test substance at challenge. Following challenge, no positive responses (grade 1 or higher) were observed on any of the test or control animals at either time point. A historical positive control study with α-hexylcinnamaldehyde (JRF Study No. 408-1-01-26618; conducted November 13 to December 20, 2020) is acceptable.	**Negative**	**A**

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap